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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/735,713	12/12/2000	D. Wade Walke	LEX-0108-USA	5588

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LEXICON GENETICS INCORPORATED
8800 TECHNOLOGY FOREST PLACE
THE WOODLANDS, TX 77381-1160

EXAMINER

SWOPE, SHERIDAN

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 03/10/2004

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/735,713

Applicant(s)

WALKE ET AL.

Examiner

Sheridan L. Swope

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's response, on November 17, 2003 to the First Action on the Merits of this case, Paper No. 11, mailed June 10, 2003, is acknowledged. It is acknowledged that applicants have amended Claims 1 and 2 and added new Claims 4-8; Claims 1-8 are pending. Claims 1-3 are hereby reconsidered and Claims 4-8 are considered on their Merits.

Specification-Objection

Objection to the abstract is withdrawn, as the abstract is required to reflect the specification, not the claims.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Rejection of Claims 1-3 under 35 U.S.C. 101 is maintained, and new Claims 4-8 are rejected under 35 U.S.C. 101, because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 1-3 were rejected under 35 U.S.C. 101 because the claimed invention is not supported by a well established utility for either the nucleic acid molecule of SEQ ID NO: 1 or any nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 2. Furthermore, the claimed invention is not supported by an asserted utility based on either a demonstrated function for the protein of SEQ ID NO: 2 or by a deduced function for said protein supported by homology to known proteins. The reasons for rejection are further described in the prior action.

Applicants argue that the present invention has a number of substantial and credible utilities. For example, while applicant argue that the polymorphism at position 68 of the

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polynucleotide set forth by SEQ ID NO: 1 could be used for forensic analysis, the presence of polymorphisms in human DNA is well established and virtually any locus on a human chromosome will exhibit one or more polymorphisms which could be so used. Applicants have not identified any particular reason for use of this particular polymorphism in forensic analysis or any particular benefit that would derive from analysis of this polymorphism. Neither have Applicants identified any particular reason for use of this particular polynucleotide in "DNA chips" for the discovery of drugs associated with human disease, as no specific human diseases have been shown to be associated with or correlated with alterations in this particular polynucleotide. Likewise, applicants have not identified any particular reason for using this polynucleotide in mapping chromosome 11.

Applicant's argue that, based on the homology of SEQ ID NO: 2 with the polypeptides identified as GenBank #NM_198185, CVSP14 of WO 02/77263, and PRTS-20 of WO 01/98468, which are putative proteases, those skilled in the art would clearly believe that SEQ ID NO: 2 is a trypsin-like protease. Since all said polypeptides were disclosed after the filing date of the instant application, Applicant's argument is only hind-sight reasoning. Furthermore, the instant application fails to assert that the polypeptide of SEQ ID NO: 2 is a trypsin-like protease; an assertion of structural similarity is not an assertion of function.

Applicant's arguments are not found to be persuasive; therefore, rejection of Claims 1-3 under 35 U.S.C. 101 is maintained. Since Claims 4-8 recite the nucleic acid molecule of SEQ ID NO: 1, vectors comprising the nucleic acid molecules of Claim 1 or encoding SEQ ID NO: 2, and host cells comprising the nucleic acid molecules of Claim 1, Claims 4-8 are also rejected under 35 U.S.C. 101 for the reasons described in the prior action and above.

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Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Rejection of Claims 1-3 under 35 U.S.C. 112, first paragraph is maintained. Because said claims are not supported by either a credible asserted utility or a well established utility, one skilled in the art clearly would not know how to use the claimed invention. Claims 4-8 are rejected under 35 U.S.C. 112, first paragraph for the same reasons.

Further rejection of Claim 1 under 35 U.S.C. 112, first paragraph, for lack of enablement, is also maintained and new Claims 5 and 8, as dependent from Claim 1, are also rejected. The specification fails to provide enablement for the use of any nucleic acid molecule comprising at least 34 contiguous bases of SEQ ID NO: 1. In support of Applicant's request for withdrawal of said rejection, they provide the following arguments. "There is absolutely no requirement that all species of an invention must have all of the exact same properties. It is well established that the enablement requirement is met if any use of the invention (or in this case, certain species of the invention) is provided. There is sufficient knowledge and technical skill in the art for a skilled artisan to be able to make and use the claimed DNA species in a number of different aspects of the invention entirely without further details in a patent specification. For example, ...to design oligonucleotide probes and primers and use them in, for example, PCR based screening and detection methods to obtain the described sequence and/or determine tissue expression patterns."

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These arguments are not found to be persuasive. The instant rejection is not based on the fact that all nucleotide species of Claim 1 do not have the same properties, but because how a person of ordinary skill in the art would use any polynucleotide comprising at least 34 contiguous bases of SEQ ID NO: 1 is not taught by either the specification or the prior art. Neither the specification nor the art teach the function of any polynucleotide comprising at least 34 contiguous bases of SEQ ID NO: 1 or the protein encoded thereby; thus a person of ordinary skill in the art would clearly not know how to use the recited polynucleotides. In addition, because the function of said polynucleotides and proteins is unknown, the use of said polynucleotides for designing oligonucleotide probes and primers for use in screening and detection methods is only potential, as what to be screened for or detected is unknown. Furthermore, many of the oligonucleotides derived from any polynucleotide comprising at least 34 contiguous bases of SEQ ID NO: 1 would be derived from completely undefined sequences, which are not derived from SEQ ID NO: 1. Clearly a person of ordinary skill in the art would not know how to make or use said oligonucleotides. Thus, rejection of Claim 1 under 35 U.S.C. 112, first paragraph, for lack of enablement, is maintained. Claims 5 and 8, as dependent on Claim 1 are rejected for the same reasons.

Rejection of Claim 1 under 35 U.S.C. 112, first paragraph, for insufficient written description, is maintained, and Claims 5 and 8, as dependent on Claim 1, are rejected. In support of Applicant's request for withdrawal of said rejection, they cite *Fiers v. Sugano* and state that "a claim describing a genus of nucleic acids by structure, formula, chemical name or physical properties sufficient to allow one of ordinary skill in the art to distinguish the genus from other materials meets the written description requirement". Applicants further state that, "the skilled

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artisan would readily be able to distinguish the claimed nucleic acids from other materials on the basis of the specific structural description provided. Polynucleotides that comprise at least 34 contiguous nucleotides of SEQ ID NO: 1 are within the genus of the instant claims, while those that lack this structural feature lie outside the genus.” This argument is not found to be persuasive because Claim 1 is rejected under 35 U.S.C. 112, first paragraph, for insufficient functional written description, not insufficient structural written description. Since, as described in the prior action, the specification does not contain any disclosure of the function of all said nucleic acid sequences, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed. Therefore, Rejection of Claim 1 under 35 U.S.C. 112, first paragraph, for insufficient written description, is maintained. Claims 5 and 8, as dependent on Claim 1, are also rejected under 35 U.S.C. 112, first paragraph, for insufficient written description.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Sheridan Lee Swope, Ph.D.

Rebecca Runt
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PRIMARY EXAMINER
GROUP 1800
1602